IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

DEBRA RUBERTI, Plaintiff, v. ETHICON, INC., and JOHNSON & JOHNSON, Defendants.	)))))))))	CASE NO. 2:20-CV-874-WKW [WO]

MEMORANDUM OPINION AND ORDER

Before the court are three pending motions. The first motion is Defendants' Motion for Partial Summary Judgment (Docs. # 52, 53), to which Plaintiff has filed a response (Docs. # 56, 57) and Defendants have filed a reply (Doc. # 59). The second motion is Defendants' *Daubert* motion seeking to exclude case-specific opinions and testimony of Dr. Ricardo R. Gonzalez, M.D. (Docs. # 42, 43), to which Plaintiff has filed a response (Docs. # 50, 51). The third motion is Defendants' *Daubert* motion seeking to exclude case-specific opinions of Dr. Keith O. Reeves, M.D. (Docs. # 54, 55), to which Plaintiff has filed a response (Doc. # 58). For the reasons stated below, all three motions are due to be granted in part and denied in part.

I. JURISDICTION AND VENUE

Subject matter jurisdiction is proper under 28 U.S.C. § 1332. The parties do not contest personal jurisdiction or venue.

II. BACKGROUND

The following facts are undisputed. (Docs. # 53 at 3; 57 at 2.) Plaintiff Debra Ruberti underwent surgery on April 16, 2012, to treat stress urinary incontinence. As part of that surgery, a pelvic mesh was implanted. The mesh, marketed as Gynemesh Tension-free Vaginal Tape - Obturator ("TVT-O"), was designed and manufactured by Defendants Ethicon and Johnson & Johnson. Plaintiff had a portion of the mesh removed on January 14, 2013, and an additional portion removed on October 29, 2013. Plaintiff alleges that she has suffered from mesh extrusion, resulting in urinary infections, urinary incontinence, bowel problems, painful sexual intercourse, vaginal bleeding, scarring, bladder spasms, pelvic pain, hip pain, and lower abdominal and groin pain.

On February 2, 2012, the United States Judicial Panel on Multidistrict Litigation ordered that cases involving allegations of defects in Ethicon's pelvic mesh products be transferred to the United States District Court for the Southern District of West Virginia and consolidated for pretrial proceedings. Transfer Order, *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-2327 (S.D.W. Va. Feb. 2, 2012), ECF No. 1. On January 25, 2013, Plaintiff direct-filed her claim

in the multidistrict proceedings in the Southern District of West Virginia. The instant motions were filed in late 2017, while Plaintiff's case was pending before that court.

On October 13, 2020, Plaintiff's case was transferred from the Southern District of West Virginia to this court. This court granted the unopposed portions of Defendants' motion for summary judgment on November 6, 2020. (Doc. # 86.) The remaining portions of that motion, as well as the two *Daubert* motions, are pending.

III. MOTION FOR SUMMARY JUDGMENT

The remaining portions of Defendants' partial motion for summary judgment are straightforward. Defendants seek summary judgment on Plaintiff's claims for negligent infliction of emotional distress (Count X), violations of the Alabama Deceptive Trade Practices Act ("ADTPA") (Count XIII), and unjust enrichment (Count XV). (Docs. # 53, 86.) Defendants argue that judgment is proper (1) as to Count X because Alabama law does not recognize an independent tort of negligent infliction of emotional distress; (2) as to Count XIII because Alabama law does not permit recovery under both ADPTA and common law; and (3) as to Count XV because Alabama law does not permit recovery under both an unjust enrichment claim and an express warranty claim.

A. Standard of Review

To succeed on a motion for summary judgment, the moving party must

demonstrate that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The court views the evidence, and all reasonable inferences drawn therefrom, in the light most favorable to the nonmoving party. *Jean-Baptiste v. Gutierrez*, 627 F.3d 816, 820 (11th Cir. 2010).

The party moving for summary judgment "always bears the initial responsibility of informing the district court of the basis for the motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This responsibility includes identifying the portions of the record illustrating the absence of a genuine dispute of material fact. *Id.* Alternatively, a movant who does not have a trial burden of production can assert, without citing the record, that the nonmoving party "cannot produce admissible evidence to support" a material fact. Fed. R. Civ. P. 56(c)(1)(B); *see also* Fed. R. Civ. P. 56 advisory committee note ("Subdivision (c)(1)(B) recognizes that a party need not always point to specific record materials. . . . [A] party who does not have the trial burden of production may rely on a showing that a party who does have the trial burden cannot produce admissible evidence to carry its burden as to the fact.").

If the movant meets its burden, the burden shifts to the nonmoving party to establish—with evidence beyond the pleadings—that a genuine dispute material to each of its claims for relief exists. *Celotex Corp.*, 477 U.S. at 324. A genuine dispute

of material fact exists when the nonmoving party produces evidence allowing a reasonable fact finder to return a verdict in its favor. *Waddell v. Valley Forge Dental Assocs.*, 276 F.3d 1275, 1279 (11th Cir. 2001).

B. Discussion

1. Negligent Infliction of Emotional Distress

Alabama law does not recognize negligent infliction of emotional distress as an independent tort. However, a plaintiff suing with normal negligence as her cause of action can recover *damages* for emotional distress, even in the absence of a physical injury. *See Flagstar Enters., Inc. v. Davis*, 709 So. 2d 1132, 1141 n.5 (Ala. 1997). Plaintiff cites authorities that discuss her ability to recover *damages* for emotional distress, but she does not cite any authority that permits negligent infliction of emotional distress to be brought as a separate *claim*.

Plaintiff's complaint includes both a count for negligence (Count I) and a count for negligent infliction of emotional distress (Count X). (Doc. # 1 at 4.) So while summary judgment is proper as to Count X, the effect of judgment on that count is minor. Under Alabama law, Plaintiff can recover any damages for emotional distress under Count I. (Docs. # 53 at 7; 57 at 4; 59 at 1–3.)

Summary judgment on Count X is due to be granted.

2. Alternative Pleading (Counts XIII and XV)

The remaining portions of Defendants' motion surround issues of alternative pleading. The parties agree that Plaintiff cannot recover under both the ADTPA and under common law. (Docs. # 53 at 9; 57 at 5–8, 59 at 3–4.) The parties also agree that Plaintiff cannot recover under both an unjust enrichment claim and an express warranty claim. (Docs. # 53 at 9–10; 57 at 8–9, 59 at 4–5.) Plaintiff's complaint includes all four claims. (Doc. # 1 at 4–5.) The questions are whether Plaintiff is permitted to plead in the alternative and, if so, how long she can persist with an alternative pleading.

As an initial note, the court agrees with *In re General Motors* and *Barcal* that the Federal Rules of Civil Procedure govern this question. *See In re Gen. Motors LLC Ignition Switch Litig.*, 257 F. Supp. 3d 372, 405 (S.D.N.Y. 2017), *modified on reconsideration*, No. 14-MC-2543 (JMF), 2017 WL 3443623 (S.D.N.Y. Aug. 9, 2017); *Barcal v. EMD Serono, Inc.*, No. 5:14-CV-01709-MHH, 2016 WL 1086028, at *5 (N.D. Ala. Mar. 21, 2016). The issue of alternative pleading is procedural. As long as Plaintiff does not recover under both alternatives, allowing her to plead and proceed with alternative claims does not enlarge her substantive rights. Under Rule 8(d) of the Federal Rules of Civil Procedure, Plaintiff may plead in the alternative and may "state as many claims or defenses as [she] has, regardless of consistency." Fed. R. Civ. P. 8(d). This rule does not violate the Rules Enabling Act or the

Constitution. *See Erie R. Co. v. Tompkins*, 304 U.S. 64, 78, 58 S. Ct. 817, 822, 82 L. Ed. 1188 (1938); *Wayman v. Southard*, 23 U.S. 1, 2, 6 L. Ed. 253 (1825) ("Congress has power to regulate the process in all cases, in the Courts of the Union.").

It is well-established that a party can proceed to trial with alternative theories of liability. *See Hemispherx Biopharma, Inc. v. Mid-S. Cap., Inc.*, 690 F.3d 1216, 1228 (11th Cir. 2012). It is not within Defendants' prerogative to force Plaintiff to choose between the theories to be presented at trial, and it is certainly not proper for Defendants to make that choice for her.

Summary judgment is proper only if Defendants are "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Defendants do not argue that recovery is impossible under Count XIII or Count XV as a matter of law. They merely argue that Plaintiff cannot recover under *both* Count XIII or Count XV *and* the respective alternative claim. But unless and until Plaintiff has recovered under one claim, Defendants are not entitled to judgment as a matter of law on the other.

Delivering jury instructions in the alternative is no foreign concept. Drafting an alternative verdict form is straightforward. There is no issue with proceeding at trial in the alternative. Summary judgment on Counts XIII and XV is due to be denied.

IV. MOTION TO EXCLUDE TESTIMONY OF DR. RICARDO R. GONZALEZ, M.D.

Defendants seek to exclude Dr. Gonzalez's testimony (1) regarding alternative treatments on the basis that the opinion is irrelevant and unreliable, (2) regarding the implanting physician's knowledge on the basis that such an opinion would be speculative and irrelevant, and (3) on the adequacy of the mesh's Instructions for Use ("IFU") on the basis that such an opinion is outside his field of expertise and would invade the province of the jury.

A. Standard of Review

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) The testimony is based on sufficient facts or data;
> (c) The testimony is the product of reliable principles and methods; and
> (d) The expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Rule 702 assigns the trial court a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."

Daubert, 509 U.S. at 589, 597; *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) ("[T]he Federal Rules of Evidence 'assign to the trial judge the task of ensuring that an expert's testimony rests both on a reliable foundation and is relevant to the task at hand.'" (quoting *Daubert*, 509 U.S. at 597)). This gatekeeping responsibility is the same when the trial court is considering the admissibility of testimony based upon "'technical' and 'other specialized knowledge.'" *Kumho Tire*, 526 U.S. at 141 (quoting Fed. R. Evid. 702).

Considering *Daubert*'s "gatekeeping requirement," the Eleventh Circuit requires district courts to engage in a "rigorous three-part inquiry" for assessing the admissibility of expert testimony under Rule 702:

> Trial courts must consider whether: "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue."

United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). These requirements are known as the "qualifications," "reliability," and "helpfulness" prongs. *See id.*

"The burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion." *Id.* And the proponent must meet its burden

by a preponderance of the evidence. *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1232 (11th Cir. 2009); *see also Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999) ("The burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." (citing *Daubert*, 509 U.S. at 592 n.10)).

As to qualifications, "experts may be qualified in various ways," including by scientific training, education, and experience. *Frazier*, 387 F.3d at 1260–61. "Whether a proposed expert's experience is sufficient to qualify the expert to offer an opinion on a particular subject depends on the nature and extent of that experience." *United States v. Cunningham*, 679 F.3d 355, 379 (6th Cir. 2012). "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee note to 2000 amendments.

Courts must also be mindful that "[e]xpertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Children & Families*, 772 F.3d 1352, 1368 (11th Cir. 2014). But "[s]o long as the expert is at least minimally qualified, gaps in his qualifications generally will not preclude admission of his testimony, as this relates more to witness credibility and thus the

weight of the expert's testimony, than to its admissibility." *Henderson v. Goodyear Dunlop Tires N. Am., Ltd.*, Nos. 3:11-CV-295-WKW, 3:12-CV-510-WKW, 2013 WL 5729377, at *6 (M.D. Ala. Oct. 22, 2013) (quoting *Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F. Supp. 2d 1293, 1304 (N.D. Ga. 2008)).

As to reliability, trial courts retain "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire*, 526 U.S. at 152. The focus of reliability "must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595. After all, "*Daubert* does not require certainty; it requires only reliability." *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1198 n.10 (11th Cir. 2010). But district courts may reject expert testimony that is based on sound methodology when "there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Finally, whether the expert testimony will assist the trier of fact in understanding the evidence or a fact in issue "goes primarily to relevance." *Daubert*, 509 U.S. at 591. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Id.* (citation and internal quotation marks omitted). Moreover, "[o]nce an expert opinion has satisfied *Daubert*, a court may not exclude the opinion simply because it believes that the opinion is not — in its view — particularly strong or persuasive." *Seamon v. Remington Arms Co., LLC*,

813 F.3d 983, 990 (11th Cir. 2016). Where the basis of expert testimony satisfies Rule 702, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

B. Discussion

1. Opinion on a Safer Alternative Design

The first point of contention surrounds a single paragraph in Dr. Gonzalez's report:

> As a safer practical/feasible alternative design to the use of the TVT-O sling, the following which would have prevented the injuries sustained by Ms. Ruberti by way of her use of the defective TVT-O mesh product: ***Nonsurgical*** (1) Kegel exercises; (2) a removable pessary device; (3) transurethral bulking agents; ***Surgical*** - (4) the Burch procedure, (5) Pubovaginal sling procedure- (autologous, cadaveric, or xenograft) or allograft sling, Repliform. Any of these procedures, instead of the Prolene polypropylene mesh used with the TVT-O would have been safer, feasible alternatives that would have reduced the risk of, or eliminated, Ms. Ruberti's risk of suffering the injuries she sustained from the defective TVT-O product. Further, a shorter, lighter weight, large pore mesh sling with less Prolene material (e.g. Ultrapro) would have been safer, feasible alternative design and would have substantially reduced the risk of her suffering from the injuries she sustained. Any of these procedures would have been proper and substantially eliminated the injuries she suffered from the defective TVT-O device.

(Doc. # 50-1 at 15.)

The parties divide this paragraph into two parts. The first part identifies other treatments and procedures that could have been used in place of a pelvic mesh

(alternative treatments), and the second identifies the specific changes to the pelvic mesh that Dr. Gonzalez believes would have made it safer (alternative designs). Defendants' argument focuses on excluding the alternative treatments, and does not quote or mention the alternative designs. (Doc. # 43 at 2–5.) Defendants accurately state that proof of alternative *treatment* is not proof of a safer alternative *design* for the challenged product. *See Hosford v. BRK Brands, Inc.*, 223 So. 3d 199, 208 (Ala. 2016).

Plaintiff does not defend the inclusion of the alternative treatments. Plaintiff only argues that the second half of the paragraph is a reliable identification of a safer alternative design. As to the first part of the paragraph, Plaintiff only says that it is "not the safer alternative design." (Doc. # 51 at 3–7.)

With Plaintiff's concession that the first half of the paragraph does not properly identify a safer alternative design, this portion of Defendants' motion is due to be granted. Dr. Gonzalez's opinion regarding alternative treatments will not be admitted as proof of a safer alternative design for the mesh. Of course, the portions of his opinion that discuss a safer alternative *design* are unchallenged by Defendants and will not be excluded by this order.

2. Testimony Regarding the Knowledge of the Implanting Physician

The challenged portion of Dr. Gonzalez's testimony consists of a single sentence: "These risks, adverse reactions, and warnings, as well as the clinical

consequences, should have been clearly stated in the IFU *so that Dr. McClinton would be fully informed*, and so Ms. Ruberti could have been properly informed." (Doc. # 50-1 at 16 (emphasis added).)

Defendants take issue with Dr. Gonzalez's mentioning Dr. McClinton, the implanting physician, by name. They argue that Dr. Gonzalez has no information by which he could draw a connection between the gaps in the IFU with the implanting physician's personal knowledge. (Doc. # 43 at 5–7.) Even assuming that Dr. Gonzalez is qualified to testify regarding the sufficiency of the IFU, he still cannot say whether or how the implanting physician used the IFU or whether the implanting physician had external knowledge regarding the risks of the mesh. Thus, it is speculative to say that Dr. McClinton, specifically, would have been "fully informed" if and only if the IFU was written according to Dr. Gonzalez's specifications. Mentioning the implanting physician by name pushes the opinion too far into the concrete world of causation and too far outside the scope of Dr. Gonzalez's expertise. Testimony from the implanting physician is more appropriate for determining what would have "fully informed" him.

Plaintiff's response confirms this view. Plaintiff states that "Dr. Gonzalez's opinion . . . is based on his review of the product Instruction for Use and other materials in this case, as well as the pertinent medical literature, his background, training, and experience as a clinician." (Doc. # 51 at 8.) Again, while this might

qualify Dr. Gonzalez to opine generally on the gaps in the IFU, it does not qualify him to opine on whether those gaps in the IFU affected the amount of information known to the specific implanting physician in this case. This part of Defendants' motion is due to be granted.

3. IFU Testimony Generally

Defendants object to all of Dr. Gonzalez's testimony regarding the sufficiency of the IFU on three bases: (1) the testimony is irrelevant because the implanting physician did not rely on the IFU; (2) the testimony is outside Dr. Gonzalez's expertise; and (3) the testimony invades the province of the jury by applying conclusory labels such as "inadequate," "insufficient," or "incomplete" to the IFU.

The implanting physician was inconclusive in his deposition as to whether the IFU played any role. As Defendants point out, he did say:

> Q: All right. At the time of Ms. Ruberti's surgery in April of 2012, did you rely on the words in the Instructions for Use to make your decision to use that device?
> A: No.
> Q: At the time of Ms. Ruberti's surgery, did you rely on the actual words in the Instructions for Use when you recommended the TVT-O?
> A: No.

(Doc. # 50-2 at 21–22.) However, his later testimony clarified that point:

> Q: There's – you've had a moment earlier to look at the Instructions For Use; is that correct? And that's Exhibit Number 12.
> A. Okay. Well, you know, I didn't – I mean, this is very voluminous.
> Q: And certainly – and a lot of this in different –
> A: Yeah. I have – I do recall seeing this.
> Q: Yes.

> A: But I didn't look at it every time I operated on somebody.
> Q: Right. Makes sense.
> A: Yeah.
> Q: But, clearly before operating on Miss Ruberti, you had plenty of opportunity and did, in fact, read the IFU; is that correct?
> Objection to form. Misstates the testimony.
> A: I – I think I have had opportunity to – to read this. And – and, certainly, she was not my first, so that I'd done it in the past. I don't remember how long before, though.

(Doc. # 50-2 at 24–25.) He later stated: "I think I had read it." (Doc. # 50-2 at 27.) He also stated that he had "been using it" and was "comfortable with it." (Doc. # 50-2 at 26.)

On this record, it is at least ambiguous as to whether the IFU was relevant to the implanting physician's decision-making process. It is plausible that the implanting physician read the IFU at some point in the past, but did not re-read the IFU at the time of Plaintiff's surgery. Additionally, Plaintiff alleges that the IFU improperly *excluded* important information, so whether the implanting physician "rel[ied] on the actual words in the Instructions for Use" is not important. Instead, the implanting physician needs to have relied on the *absence* of words from the IFU. Thus, the physician's answers to the first two questions are inconsistent with the rest of his testimony and, strictly speaking, not conclusive on the issue of causation.

Under Rule 104(b) of the Federal Rules of Evidence, admissibility need only be supported by evidence "sufficient to support a finding that the fact does exist." Fed. R. Evid. 104(b). The testimony provided by the implanting physician is

sufficient to support a finding that he read and relied on the IFU. It is also sufficient to support a finding that he did not. Instead of guessing what the implanting physician meant in his testimony, that matter is left to the jury. A ruling on this issue would be premature.

As to Dr. Gonzalez, Defendants argue that he is not qualified to opine on the sufficiency of the IFU. Plaintiff provides only a conclusory statement in rebuttal: "Dr. Gonzalez is qualified by 'knowledge, skill, experience, training, and education' to render medical opinions in this case, including but not limited to Safer Alternative Design, and the adequacy of the warnings of the risks and adverse reactions contained in the Instructions for Use." (Doc. # 51 at 11.) The materials submitted by Plaintiff, however, do not reveal any special expertise of Dr. Gonzalez on drafting IFUs. Dr. Gonzalez is extensively qualified in urology by his training, education, and experience—but the question is, how far can a doctor's IFU testimony go without any special expertise in the drafting of IFUs?

The precedent on this issue is straightforward in some ways. If the doctor does not practice in the relevant specialty or use the product regularly, then that opinion will not be reliable. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 969–70 (10th Cir. 2001); *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1329 (M.D. Fla. 2015). Further, it is clear that a doctor with no experience in drafting IFUs and no experience with the regulatory structure for approving an IFU

cannot testify as to the regulatory or legal sufficiency of an IFU. *See Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *5 (S.D.W. Va. Feb. 7, 2015); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D.W. Va. 2014).

It is also clear that a doctor in the relevant specialty may testify as to the risks of the device and whether those risks were identified in the IFU. *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-02327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016). What is not so clear is whether the expert can testify that those missing risks therefore made the IFU "incomplete" or "inaccurate." The Southern District of West Virginia stated in a related case that: "While an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re Ethicon*, 2016 WL 4536885, at *2.

However, the Southern District of West Virginia has said essentially the opposite under similar circumstances. *See Wise*, 2015 WL 521202, at *5 ("While I have found Dr. Ostergard unqualified to opine on FDA regulations and whether a product label satisfies those regulations, *see Tyree, et al. v. Boston Scientific Corp.*, No. 2:12–cv–08633, 2014 WL 5320566, at *36–37 (S.D.W. Va. Oct. 17, 2014), the plaintiffs have confirmed that Dr. Ostergard will not testify on these topics. Rather, as indicated by his expert report, Dr. Ostergard will testify about the risks he

perceives that the Avaulta poses to patients, and he will opine that the Avaulta IFU did not convey these risks. A urogynecologist like Dr. Ostergard is qualified to make this comparison."); *Huskey*, 29 F. Supp. 3d at 719 ("Ethicon first challenges Dr. Blaivas's qualifications to give these opinions because Ethicon argues that Dr. Blaivas is not an expert on product warnings. But Dr. Blaivas need not be an expert on product warnings *per se*. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT–O and whether those risks were adequately expressed on the TVT–O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warning and—it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits of the TVT–O was when the warnings were published." (quotation marks omitted) (quoting *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000))). Rendering an opinion on the "completeness" of an IFU, *see Huskey*, 29 F. Supp. 3d at 719, is impossible without identifying "what information should or should not be included in an IFU," *see In re Ethicon*, 2016 WL 4536885, at *2.

The expert's ability to testify as to the "completeness and accurateness" of the warning under these circumstances is well-settled. *See, e.g.*, *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH,

2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs. Thus, Dr. Bercy-Roberson is qualified to render an opinion as to the drug label's completeness and accurateness." (alterations adopted) (quotation marks omitted) (citation omitted) (quoting *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000))). Thus, to the extent that identifying information that "should or should not" have been included in the IFU is necessary for explaining how the warning was incomplete, the court declines to follow the Southern District of West Virginia's ruling in *In re Ethicon*. *See* 2016 WL 4536885, at *2

Thus, Dr. Gonzalez is qualified to testify as to the risks of the TVT-O, whether those risks were fully explained on the IFU, and therefore whether the IFU can be described as complete or accurate. Dr. Gonzalez may explain any potential incompleteness or inaccuracy of the IFU by referring to specific risks that were not identified, but he may not present an alternative IFU or attempt to engage in an IFU redrafting exercise. Dr. Gonzalez is not qualified to opine on whether the IFU comported with law or regulation.

Testimony consistent with the above standards would not invade the province of the jury. To the extent that Defendants' *Daubert* motion seeks to exclude such testimony, it is due to be denied.

V. MOTION TO EXCLUDE TESTIMONY OF DR. KEITH O. REEVES, M.D.

Defendants seek to exclude Dr. Reeves's testimony (1) regarding general causation because Plaintiff failed to designate Dr. Reeves as a general causation expert, (2) to the extent that the testimony was not included in Plaintiff's Rule 26 report, (3) regarding Dr. Reeves's opinion on the IFU, (4) regarding Ultrapro as a safer alternative to TVT-O, and (5) regarding Ethicon's knowledge or corporate intent. (Doc. # 55 at 1–2.)

A. Standard of Review

This motion is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as fully laid out above.

B. Discussion

1. Failure to Designate Dr. Reeves as a General Expert

Defendants' argument in the first part of their motion hinges entirely on a single fact. They claim that, in Plaintiff's Rule 26(a)(2) report, "Dr. Reeves is identified solely as a 'Specific Causation Expert.'" (Doc. # 55 at 3.) However, the words "specific causation" are never used in either Plaintiff's report or Dr. Reeves's report. Instead, Plaintiff refers to Dr. Reeves as a "case specific" expert. (Doc. #

55-3 at 4.) Plaintiff's case, of course, is far broader than just specific causation, and Plaintiff did not hide the breadth of Dr. Reeves's proposed testimony. Plaintiff's Rule 26(a)(2) report says that "Plaintiff hereby incorporates by reference Dr. Reeves Expert Report and all subparts and attachments thereto." (Doc. # 55-3 at 4.) To the extent that Dr. Reeves's report identified opinions or materials that extend beyond specific causation, those were duly incorporated into Plaintiff's report. Defendants had sufficient notice that Dr. Reeves would present such opinions. This part of Defendants' motion is therefore due to be denied.

2. Opinions Not Contained in the Rule 26(a)(2) Report

Plaintiff is correct that Dr. Reeves may contradict his written report at trial. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582209, at *5 (S.D.W. Va. Sept. 1, 2016) ("To the extent an expert offers *inconsistent* testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence." (emphasis added)). However, that does not mean that Dr. Reeves may offer *additional* testimony outside his Rule 26 report. Rule 26 is very clear on this point: "The report *must* contain . . . a *complete* statement of *all* opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i) (emphasis added).

The portion of the *In re Ethicon* opinion cited by Plaintiff is distinguishable because the witness testimony at issue there was not solely expert testimony. *See In re Ethicon*, 2014 WL 186872, at *9. The expert there was also a fact witness, and the question was whether a Rule 26 report needed to be submitted in the first place. *Id.* That is not the case here.

Dr. Reeves may not testify regarding any subjects or opine on any topics that are not identified in his expert report. This part of Defendants' motion is due to be granted.

3. Opinion Regarding the IFU

Dr. Reeves will be subject to the same restrictions discussed above for Dr. Gonzalez as pertains to the IFU testimony. Dr. Reeves is extensively qualified in obstetrics and gynecology by his training, education, and experience and is qualified to opine on the IFU to the same extent as Dr. Gonzalez.

4. Opinion Regarding Ultrapro

Dr. Reeves has opined that "a shorter, lighter weight, large pore mesh sling with less Prolene material (e.g. Ultrapro) would have been a safer, feasible alternative design and would have substantially reduced the risk of [Plaintiff] suffering from the injuries she sustained." (Doc. # 55-1 at 21.) Defendants attack this opinion on the basis that Ultrapro has never been used to treat stress urinary

incontinence and Dr. Reeves's opinion "is therefore rank speculation." (Doc. # 55 at 5–6.)

Whether a particular treatment is actually used in the medical field is a matter of "general acceptance." But "general acceptance" is not the ultimate criterion for determining the admissibility of expert testimony. That was exactly the cursory inquiry that the Supreme Court rejected in *Daubert*. *See* 509 U.S. at 589; *contra Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923). Of course, general acceptance "can yet have a bearing on the inquiry," *Daubert*, 509 U.S. at 594, but the key question is whether a qualified expert, using a reliable methodology, has helpfully applied that methodology to the facts of the case. *Frazier*, 387 F.3d at 1260. If the expert relies on a solid methodology, then a lack of field usage imparts nothing more than a dose of skepticism. *See Daubert*, 509 U.S. at 594.

Defendants state that Dr. Reeves's opinion is "unsupported by any research or even anecdotal clinical evidence." (Doc. # 55 at 6.) However, as Plaintiff notes, Dr. Reeves cites several studies in his expert report that explain the benefits of a lightweight, larger-pore, monofilament mesh. Dr. Reeves's report clearly engages with the medical and scientific literature and appears to be based on reliable research and studies. Dr. Reeves's opinion meets the standard set forth in *Daubert* and is proper expert opinion testimony.

5. Ethicon's Corporate Knowledge and State of Mind

The Southern District of West Virginia and the parties all cite the same standard:

> While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—[the company]'s knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.

In re C.R. Bard, Inc., 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *on reconsideration in part* (June 14, 2013).

Defendants seek to exclude two categories of evidence under this standard. First, they seek to exclude Dr. Reeves's opinion as to what Ethicon "was aware of." Second, they seek to exclude Dr. Reeves's comment that Ethicon engaged in a "disturbing pattern" of failing to disclose the risks of TVT-O. (Doc. # 55 at 6.) Plaintiff responds only by claiming that these two portions of Dr. Reeves's report "explain the basis for Dr. Reeves' opinions as to the IFU." (Doc. # 58 at 13.)

As explained above, Dr. Reeves can opine as to the IFU within specified limits. Dr. Reeves can testify as to the risks of the TVT-O, whether those risks were fully explained on the IFU, and therefore whether the IFU can be described as complete or accurate. Whether Ethicon knew of these risks may be a foundation that Plaintiff must lay before this opinion is relevant, but it certainly is not information

that Dr. Reeves himself must rely on in order to opine in these areas. The existence of the mesh's risks does not depend on whether Defendants knew of them. Whether the risks are reflected in the IFU does not depend on whether Defendants knew of them. Thus, testimony regarding Defendants' corporate knowledge would not be helpful for the jury to understand Dr. Reeves's IFU opinion. Additionally, the corporate knowledge of Defendants is outside Dr. Reeves's expertise. Dr. Reeves can discuss whether the risks were known to the scientific or medical community, but any testimony that states that *Defendants* knew of the risk is not appropriate. Dr. Reeves is not an expert in sifting through corporate documents and ascribing knowledge to corporate actors. That exercise is better left to the jury.

Dr. Reeves's "disturbing pattern" comment similarly goes beyond his expertise. Dr. Reeves may testify that the IFU was incomplete, and he may testify that Defendants had a "pattern" of incomplete IFUs if that is supported by the record, but it is not appropriate for Dr. Reeves to assert that Defendants' behavior is "disturbing." That conclusion is not based on Dr. Reeves's scientific training, education, or experience; nor is it the kind of statement that can be based on reliable principles and methodology. Simply put, it is not a scientific or medical opinion, and it is not necessary or helpful for Dr. Reeves's testimony. It would improperly invade the province of the jury for Dr. Reeves's to offer his non-expert personal opinion on the behavior of Defendants.

This portion of Defendants' motion is due to be granted.

VI. CONCLUSION

For the reasons stated above, it is ORDERED that Defendants' partial motion for summary judgment (Doc. # 52) is GRANTED IN PART and DENIED IN PART; Defendants' motion to exclude case-specific opinions and testimony of Dr. Ricardo R. Gonzalez, M.D. (Doc. # 42) is GRANTED IN PART and DENIED IN PART; and Defendants' motion to exclude case-specific opinions and testimony of Dr. Keith O. Reeves, M.D. (Doc. # 54) is GRANTED IN PART and DENIED IN PART as follows:

1. Summary judgment is GRANTED as to Count X, Plaintiff's claim for negligent infliction of emotional distress;

2. Summary judgment is DENIED as to Counts XIII and XV, Plaintiff's claims for violations of the Alabama Deceptive Trade Practices Act and unjust enrichment;

3. Ricardo R. Gonzalez, M.D., may not testify that alternative treatments are proof of a safer alternative design for the mesh. Dr. Gonzalez's testimony that does identify a safer alternative design for the mesh ("shorter, lighter weight, large pore mesh sling with less Prolene material") is not excluded under this order;

4. Ricardo R. Gonzalez, M.D., may not testify whether the TVT-O Instructions for Use impacted the amount of information known to the implanting physician;

5. Ricardo R. Gonzalez, M.D., is qualified to testify as to the risks of the TVT-O, whether those risks were fully explained on the IFU, and therefore whether the IFU can be described as complete or accurate. Dr. Gonzalez may explain any potential incompleteness or inaccuracy of the IFU by referring to specific risks that were not identified, but he may not present an alternative IFU or attempt to engage in an IFU redrafting exercise. Dr. Gonzalez may not opine on whether the IFU comported with law or regulation;

6. Keith O. Reeves, M.D., may not testify on any subject matter or opine in any areas not contained in his Rule 26(a)(2) report;

7. Keith O. Reeves, M.D., may not testify whether the TVT-O Instructions for Use impacted the amount of information known to the implanting physician;

8. Keith O. Reeves, M.D., is qualified to testify as to the risks of the TVT-O, whether those risks were fully explained on the IFU, and therefore whether the IFU can be described as complete or accurate. Dr. Reeves may explain any potential incompleteness or inaccuracy of the IFU by referring to specific risks that were not identified, but he may not present an alternative IFU or attempt to engage in an IFU

redrafting exercise. Dr. Reeves may not opine on whether the IFU comported with law or regulation;

9. Keith O. Reeves, M.D., may not testify as to the knowledge or state of mind of Defendants; and

10. Keith O. Reeves, M.D., may not apply ethical labels to Defendants' conduct, such as by describing Defendants' conduct as "disturbing."

DONE this 29th day of November, 2021.

/s/ W. Keith Watkins
UNITED STATES DISTRICT JUDGE